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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/933,256	08/20/2001	Ramesh B. Jayaraman	018881.0123	5271

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EXAMINER

BARRETT, THOMAS C

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 08/15/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/933,256

Applicant(s)

JAYARAMAN ET AL.

Examiner

Thomas C. Barrett

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-49 is/are pending in the application.
- 4a) Of the above claim(s) 21-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,20 and 46-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-2, 4-20 and 46-49 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 8 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4 and 8 are indefinite because they seem to contradict claim 1, which they are dependent ^{on} ~~one~~ ₁. Claim 1 claims the blood interface surface as the "first surface" while claims 4 and 8 claim a different surface as the "first surface".

Claim 12 is indefinite because it recites, "wherein said graft is a vascular graft, a stent-graft or a vascular patch". The preamble recites that the graft is a vascular graft. Claim 12 as written implies that a stent-graft or a vascular patch is other than a vascular graft. It is unclear and therefore indefinite what the metes and bounds of claim 12 are.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4-10, 12, and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Nyilas (3,562,352). Nyilas discloses a polyurethane coated woven PET (DACRON) cylindrical vascular graft for use in a vessel having an internal diameter of more than 6 mm (col. 7, line 73- col. 8, line 14). The polyurethane would inherently permeate into a mesh “core zone”. Furthermore, the Nyilas vascular graft has the polyurethane coatings on both the “first” and “second” surfaces, either or both of which may permeate into the mesh “core zone” and still meet the structural limitations of the claims.

Claims 1, 16, and 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Jayaraman (5,298,276) as cited in applicant’s IDS. Jayaraman discloses a vascular graft comprising: a PET (polyethyleneterephthalate) knit core coated with a soft segment of polysiloxane and a hard segment of polyurethane further comprising 1,4-butanediol (col. 6, line 60- col.8, line 49). The coating can be applied to the outside or first surface and allowed to penetrate to the inside or second surface (col. 6, lines 16-27 and Fig. 14). Because the coating is on both the inner and outer surfaces, it doesn’t matter which surface the coating permeated from, the structural limitations of the claims are still met.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13-15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jayaraman (5,298,276) as above in view of Thoratec (Thoralon). Jayaraman discloses a vascular graft comprising a PET (polyethyleneterephthalate) knit core however Jayaraman fails to disclose the core coated with Thoralon, a coating that comprises polyurethane urea blended with a siloxane containing a surface modifying additive. Thoratec teaches the use of Thoralon as a biomaterial, which minimizes clotting and inflammatory responses. It would have been obvious to one of ordinary skill in the art to combine the teaching of Thoralon as a biomaterial, as taught by Thoratec, to a vascular graft comprising a PET as per Jayaraman, in order to minimize clotting and inflammatory responses. Furthermore, Jayaraman in view of Thoratec fails to disclose the soft segment having a molecular weight of about 2,000 g/mole.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art a coating with a soft segment having a molecular weight of about 2,000 g/mole. Applicant has not disclosed that the molecular weight provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform

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equally well with the molecular weight of the soft segment of a Thoralon coating because the applicant admits it to be a preferred embodiment. Therefore, it would have been obvious to one of ordinary skill in the art to modify the vascular graft comprising a PET and polyurethane coating to obtain the invention as specified in claim 17.

Claims 1, 11, and 46-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hogendijk et al. (5,713,907) in view of Nyilas as above. Hogendijk et al. discloses a PET vascular graft for use as an AAA stent graft in humans (col.7, lines 24-28, col. 4, lines 12-16 and Fig. 1) however Hogendijk et al. fails to disclose the PET coated with a polyurethane on the blood interface surface. Nyilas teaches a polyurethane coated PET vascular graft, which has a high degree of blood compatibility (col. 1, lines 23-30). It would have been obvious to one of ordinary skill in the art to combine the teaching of a polyurethane coating, as taught by Nyilas, to a PET vascular graft for use as an AAA stent graft as per Hogendijk et al., for a high degree of blood compatibility.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas C. Barrett whose telephone number is (703) 308-8295. The examiner can normally be reached Tuesday-Friday between 9:00 A.M. and 6:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (703) 308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3580 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308 0850.



Thomas Barrett
August 9, 2003



David H. Willse
Primary Examiner